

### **REMARKS/ARGUMENTS**

Claims 1, 4-10, 12-14, 24-30 are pending. Claims 1, 13-14 and 24-27 are amended. Claims 28-30 are new. Support for amended claim 1 can be found at least in the specification, as originally filed, on page 4, line 11. Support for amended claims 24-26 can be found at least in the specification, as originally filed, on page 4, lines 9-11 and page 6, lines 14-16. Claims 13-14 and 27 were amended to clarify the invention. New claims 28-30 find support in at least the claims as originally filed. More specifically, claim 28 finds supports at least in the specification, as originally filed, on page 3, lines 12-13. Support for new claim 29 can be found at least in the specification, as originally filed, on page 4, lines 35-37. Support for claim 30 can be found at least in the specification, as originally filed, on page 4, line 11.

No new matter has been added.

#### **Specification**

The specification has been amended providing a new sequence listing and is attached hereto.

#### **Remarks regarding 35 USC 112**

##### **Indefiniteness**

The Examiner asserts that claims 23-26 are indefinite because the "appear[s] to claim identical subject matter to that of claim 1" (05 May 2006 Office Action, page 3). While neither agreeing with the Examiner's reasons for or correctness of the rejection, Applicants canceled claim 23 and amended claims 24-26. Accordingly, the rejection is moot and Applicants respectfully request its withdrawal.

##### **New Matter**

The Examiner asserts that claims 25-27 recite new matter. Applicants respectfully disagree. The amendments to claims 25-26 render their rejection moot. Nonetheless, support for the instant amendments to claims 25-26 can be found at least in the specification, as

originally filed, on page 4, lines 9-11 and page 6, lines 14-16. Support for claim 27 can be found at least in the specification, as originally, filed, on page 12, lines 24-42 and page 15, lines 3-6. Accordingly, the rejection is moot and applicants respectfully request its withdrawal.

### **Written Description**

Claims 1, 4-14 and 23-27 stand rejected for allegedly failing to meet the written description requirement. The Examiner asserts that claims contain subject matter not described in the specification in such a way to reasonably convey to one skilled in the art that the Applicants had possession of the claimed invention at the time of filing. Applicants respectfully disagree.

To satisfy the written description prong of 35 USC §112 ¶1, the specification must only describe the invention in sufficient detail so that one skilled in the art can clearly conclude that “the inventor invented the claimed invention” (*Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)). No particular form of disclosure is required, but “the description must clearly allow persons of ordinary skill in the art to recognize that [the patentee] invented what is claimed” (*In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)) (citing *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976)).

The Federal Circuit stated in *Capon v. Eshhar* that “[t]he ‘written description’ requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way (418 F.3d 1349 (Fed. Cir. 2005)). As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution” (*Id.* at 1358). In overturning a BPAI decision, which relied on similar rejection reasons as stated in the instant Office Action, where both parties to an interference had all claims in their respective patents cancelled for failing to meet the written description requirement, the court stated that “[t]he Board erred in refusing to consider the state of the art of the scientific knowledge” and when citing *Lilly* and *Fiers* spoke of rulings in view of a “wish” list provided in said inventions, and not the state of the relevant art (*Id.* at 1357). Additionally, the court stated, that “[i]t is not necessary that every permutation with a generally operable invention be effective

in order for an inventor to obtain a generic claim” and both parties were lauded because they “present[ed] not only general teachings... but also specific examples” (*Id.* at 1359).

Applicants respectfully assert that the instant specification complies with all the aforementioned requirements at least because it allows one of ordinary skill in the art to practice the instant invention commensurate with the claims. Applicants meet the “general teachings” prong by disclosing summary information such as the function of desaturases, fatty acids and triglycerides, and general molecular biology techniques, and the “specific examples” prong by disclosing a specific example of the novel desaturase for the synthesis of conjugated fatty acids, SEQ ID NO: 1. In view of *Capon*, and the state of the art of biotechnology at the time of filing, the specification fully complies with all written description requirements.

Further, the Examiner states on:

1) page 6 of the 29 July 2004 Office Action that “[t]he specification only sets forth the desaturase of SEQ ID NO:2,” and

2) page 5 of the 11 August 2005 Office Action that “[t]he desaturase of SEQ ID NO:2 is not sufficient to define the genus”

Applicants respectfully assert that the Examiner has erroneously mandated a quantifiable number of species. Any requirement for a mandatory number of species is contrary to USPTO practice and Federal Circuit precedent, and as such, the Examiner's statement indicating an insufficiency in the number disclosed in the instant specification is in error. If however, contrary to Applicants assertions above, the Examiner has personal information not of record used to determine “sufficient” numbers of examples, Applicants respectfully request an Examiner's affidavit, as set forth in MPEP 1.104(c)(D)(2), indicating the use of personal knowledge and allowance for Applicants to respond to said personal knowledge. Additionally, further application of *Capon* is required here because the skill and knowledge in the field at the time of filing was such that the species disclosed in the instant specification provide sufficient description by actual reduction to practice. Consequently, the instant invention has been sufficiently disclosed and sufficiently supported by experimental data wherein sufficient written description for the entire genus based on the applicable standards is provided. Applicants

respectfully assert that the Examiner has applied an erroneous standard for claiming a genus and that they are entitled to claim additional embodiments which are not represented by individual species, i.e. the genus from the species recited.

Moreover, the MPEP states that a "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces" and as such, a single species may be enough to identify the entire genus (*See*, MPEP 2163.II.A.3.a.ii.). Indeed, the claims are written in such a manner that the problems of insufficient numbers as described by the Examiner in the Office Actions should not apply. Applicants respectfully assert that the instant specification fully complies with all the aforementioned requirements because it allows one of ordinary skill in the art to practice the instant invention.

The Federal Circuit reaffirmed the long standing edict described above regarding the lack of a requirement of examples this past spring in *Falkner v. Inglis* (448 F.3d 1375 (Fed. Cir. 2006)). The court asserted that "[f]irst, it is clear that the absence of examples ... does not render the written description inadequate" (*Id.* at 1366) and quoted *LizardTech, Inc. v. Earth Resource Mapping, PTY, Inc.* (424 F.3d 1336, 1345 (Fed Cir. 2005))(internal quotations omitted) stating that "[a] claim will not be invalidated on *section 112* grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language." Indeed, the court, in accordance with prior case law, held that "examples are not necessary to support the adequacy of a written description" (*Id.*). Despite the fact that the Applicants are not required to provide examples for an adequate disclosure, Applicants nonetheless submitted at least SEQ ID NO: 1 and SEQ ID NO: 2 to fulfill the requirements under 35 USC 112 ¶1.

*Falkner* also addresses the requirement for a structural description of the claimed biological substance. The court held that "there is no per se rule that an adequate written description of an invention that involves a biological macro molecule must contain a recitation of a known structure" (*Id.*). In light of the aforementioned, Applicants respectfully assert that the Examiner erroneously rejected the instant claims on grounds that "given the lack of written

description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time the application was filed" (Office Action 29 July 2004, page 7). In fact, upon application of the proper standard under 112, Applicants respectfully assert that the skilled artisan, at least from the disclosure in the specification, would have knowledge of other desaturase genes and proteins, and their structures and physical characteristics. Thus, the rejection is moot.

The instant disclosure, analyzed in view of the MPEP and at least *Capon* and *Falkner*, provides an adequate written description for one of ordinary skill in the art to practice the instant invention. The instant disclosure fulfills the requirements of *Capon* with "general teachings" and "specific examples." Further, as per *Falkner*, no examples are necessary but are provided nonetheless and no recitation of known structures are required because one of ordinary skill in the art would have this knowledge. Consequently, examined in light of the state of the art, the skilled artisan would clearly conclude that the inventor "at the time the application was filed, had possession of the claimed invention" and thus meets the requirements of the written description prong of 35 USC 112.

### **Enablement**

Claims 1, 4-14 and 23-27 stand rejected for allegedly being non-enabled. The Examiner asserts that the specification, while enabling for a nucleic acid encoding the calendulic acid desaturase of SEQ ID NO: 2, does not enable a skilled artisan to make or use the invention commensurate in scope with the claims. Applicants respectfully disagree.

Regarding the enablement requirement of §112, the Federal Circuit held that "[t]he specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, given what they already know, the specification teaches those in the art enough that they can make and use the invention without 'undue experimentation'" (*Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. (2003))). Applicants respectfully assert that the claims are fully enabled by the specification of the application in

combination with the general knowledge of one of ordinary skill in the art and offer the following remarks.

The Examiner sets forth a number of reasons for imposing the enablement rejection<sup>1</sup>. However, all these reasons boil down to one issue. Namely, the Examiner is asserting that homology alone is not a sufficient determinant of enablement. Applicants respectfully assert that the Examiner has provided no argument or case law against the claimed invention. No claims recite that homology alone is determinative of function. Applicants claims require a functional component as well as a percentage homology. Claim 1 recites, in part, "without reducing the enzymatic activity of the polypeptides to less than 10% of the activity of the polypeptides with the amino acid sequence shown in SEQ ID NO: 2" thus requiring a specific level of enzymatic activity unmentioned in the Examiner's cited art examples. Moreover, sequences that encode enzymes with the high percentage homologies to that of the a desaturase or a conversion of a desaturase to a hydroxylase fail to address enablement of a desaturase with a specific activity level. Accordingly, Applicants respectfully assert that the Examiner has erroneously rejected the instant claims as non-enabled using an improper interpretation of the art and the claims and that the rejection is moot.

Further, the Federal Circuit recently stated in *Falkner*, that "[a] patent need not teach, and preferably omits, what is well known in the art." (448 F.3d 1357, 1365 (Fed. Cir. 2006))(quoting *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987)). *Falkner* acknowledges the coming of age of molecular biology by asserting that a chemical structure required for a claim does not always have to be provided by a specification and in the application. Possession of such details can be imputed if shown in a publication before the filing date which, for example, is exemplified in this application by Chin et al. *Journal of Food Composition and Analysis*: 5, 185-197 (1992).

Indeed, the specification discloses the techniques one of ordinary skill in the art would use when attempting to modify SEQ ID NO: 1. The Examiner is directed to, for example, the

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<sup>1</sup> For example, in the Office Action of 29 July 2004, on page 7, the Examiner asserts that "[s]equence homology is not sufficient to predict function of encoded sequences." On page 8, the Examiner states that "Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved."

following in the specification as originally filed:

To achieve optimal expression of heterologous genes in organisms, it is advantageous to alter the nucleic acid sequences in accordance with the specific codon usage used in the organism. The codon usage can be determined readily by using computer evaluations of other, known genes of the organism in question (page 5, line 44 to page 6, line 2); and

certain amino acids may be replaced by others with similar physico-chemical properties (spatial dimension, basicity, hydrophobicity and the like). For example, arginine residues are exchanged for lysine residues, valine residues for isoleucine residues or aspartic acid residues for glutamic acid residues. Alternatively, it is possible to exchange the sequence of, add or remove one or more amino acids, or two or more of these measures may be combined with each other (page 6, lines 17-25).

Additionally, the skilled artisan would know how to attempt to mutate known sequences. For example, one of ordinary skill can introduce conservative amino acid substitutions at one or more predicted nonessential amino acid residues. Applicants respectfully assert that a conservative amino acid substitution is known by the skilled artisan as one in which the amino acid residue is replaced with an amino acid residue having a similar side chain. Further, families of amino acids having similar side chains are well known to the skilled artisan as is their substitution in amino acid modifications.

In addition to the instant disclosure, applying *Falkner*, at least all known active sites, conserved regions and functionally essential amino acids would be known and available to one attempting to practice the claimed invention. Applicants respectfully assert that one of ordinary skill in the art would know what regions of the desaturase could or could not be modified and maintain function based on what is disclosed in the specification and what one of ordinary skill in the art is deemed to know. Moreover, implicit in the disclosure are functional desaturase enzymes. Further, data related to crystalline structure and protein folding from substituted and unsubstituted enzymes would also be known allowing for modification of the amino acid sequence. The skilled artisan is charged with knowledge of all the relevant art existing at the time of filing, and as such, would not require undue experimentation to practice the instant invention. Indeed, experiments such as those needed to create functional desaturase enzymes are

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commonly performed in laboratories across the country.

The aforementioned experimentation is routine for one skilled in the art. It must be appreciated that merely because experimentation may be "difficult and time consuming," the Federal Circuit fails to demand that the experimentation stand rejected as undue (*Falkner* at 1365) (quoting from the Board of Patent Appeals and Interferences decision on appeal).

In sum, Applicants respectfully assert that the instant claims are enabled based upon the requirements of §112, the MPEP and the rulings handed down from the Federal Circuit. One of ordinary skill in the art is able to practice the instant invention without undue experimentation based on a combination of the contents of the instant specification when analyzed by the skill in the art at the time of filing.



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**Conclusion**

Applicants respectfully submit that the present application is in condition for allowance, which action is courteously requested. Please charge the two-month extension fee to the credit card listed on the enclosed Form PTO-2038. Please charge any shortage in fees due in connection with the filing of this paper to Deposit Account 14.1437. Please credit any excess fees to such account.

Respectfully submitted,



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